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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.,

Plaintiff and Counterclaim-Defendant,

vs.

NATERA, INC,

Defendant and Counterclaim-Plaintiff.

Case No. 21-cv-04062-EMC

NATERA'S MOTION *IN LIMINE* NO. 2 TO EXCLUDE EVIDENCE OR ARGUMENT THAT NATERA HAD ANY EFFECT ON MOLDX'S EVALUATION OF REVEAL FOR MEDICARE APPROVAL

REDACTED FOR PUBLIC FILING

Pretrial Conference:
Date: June 28, 2023
Time: 3:00 pm
Ctrm: 5 – 17th Floor
Judge: Hon. Edward M. Chen

Trial:
Date: July 24, 2023

[redacted]

I. INTRODUCTION

Natera moves *in limine* to exclude evidence or argument that Natera had any effect or impact on Medicare coverage approval for Reveal, including any argument, evidence, or suggestion that Natera caused any alleged "delay" in this process.

Coverage approval through the Medicare MolDX program is a complex and involved process controlled by an independent, third-party organization ("MolDX") staffed with scientists and medical professionals. Nevertheless, Guardant has sought to blame Natera for the timeline of Reveal's evaluation by MolDX, which began in April 2021 and resulted in partial approval in August 2022. Guardant argues that, [redacted] Natera somehow single-handedly caused MolDX to delay what Guardant speculates would have otherwise been an almost immediate approval. Any evidence or argument to this effect should be excluded under at least Federal Rules of Evidence 401, 402, 403 and 602.

First, any alleged effect that Guardant speculates Natera may have had on MolDX's evaluation of Reveal has no relevance to the issues in this case and should be excluded under Rule 401 and 402. [redacted] cannot be the basis of liability for false advertising. And Guardant's damages expert does not rely on Reveal's purported Medicare coverage delay in his damages calculations. This irrelevant argument should be excluded.

Second, any argument falsely suggesting Natera "delayed" MolDX's approval of Reveal should be excluded under Federal Rule of Evidence 602. There is no admissible evidence that MolDX was influenced ***in any way*** by Natera. The only "evidence" Guardant has pointed to is purely speculative testimony from its employees about [redacted] But Guardant's 30(b)(6) witness on Medicare coverage issues, Mr. McCoy, conceded he had "no direct evidence" of any such bias affecting MolDX, and further admitted MolDX told him it would not take [redacted] Other Guardant witnesses corroborated this account.

What the evidence actually shows is that—contrary to Guardant's claims now—Guardant knew even ***before*** submission to MolDX that approval was not "guaranteed" and reimbursement

[redacted]

could be denied. It also shows that, in evaluating Reveal, MolDX exercised its own independent expertise and judgment, and came to its own conclusions about deficiencies in the Parikh Study data—on which it relied to initially reject Reveal.

Third, allowing Guardant to present evidence or argument on any purported Natera-induced "delay" of MolDX approval should be excluded under Rule 403. If Guardant is allowed to assert—counter-factually—[redacted] to "delay" Medicare reimbursement for Reveal, Natera will be forced to spend precious trial time rebutting this falsehood by explaining the complex regulatory scheme that underlies Medicare reimbursement, the role Palmetto GBA and the MolDX Program play in that scheme, the process for obtaining approval, and the specific facts regarding what actually happened during MolDX's review of Reveal. The unavoidable mini-trial will be a substantial waste of time and threatens to confuse the jury. By taking time away from relevant issues, it will also unduly prejudice Natera.

For all these reasons, Guardant should be precluded from arguing or suggesting Natera caused or contributed to the purported "delay" in Medicare approval for Reveal.

II. BACKGROUND

The MolDX Program is administered by Palmetto GBA, an independent organization responsible for Medicare coverage decisions. Ex. 5 (McCoy Dep. Tr.) at 202:4-19. The Program "was developed in 2011 to identify and establish coverage and reimbursement for molecular diagnostic tests."[1] It is staffed with trained scientists, including M.D.'s and Ph.D.'s,[2] who evaluate technical submissions as part of determining Medicare coverage under certain coverage policies. Ex. 5 (McCoy Dep. Tr.) at 202:4-19. At a high level, the test evaluation process involves, among other things, an in-depth technical analysis of clinical and analytical data for the test under consideration. MolDX may—as it did when evaluating Reveal—directly engage with the test provider over technical concerns and questions about the test and/or the submitted data.

Natera's Signatera test has been approved for full Medicare coverage by MolDX since

[1] *MolDX Program (Administered by Palmetto GBA)*, Palmetto GBA, https://www.palmettogba.com/MolDx.

[2] MolDX, Frequently Asked Questions (September 21, 2022), https://www.palmettogba.com/palmetto/moldxv2.nsf/DID/9A7MFG4181.

[redacted]

September 2020, with MolDX's evaluation beginning in 2019. Signatera's approval gave rise to a policy decision—a Local Coverage Decision (LCD)—that permitted other MRD tests for CRC, like Reveal, to also be approved thereafter if they met certain requirements.

Guardant's test, Reveal, was submitted under the already-approved Signatera policy in December 2021. *See* Ex. 5 (McCoy Dep. Tr.) at 148:22-149:12. In order to establish test sufficiency, Guardant had to show, among other things, that Reveal is equivalent or superior in performance to the test already approved for coverage (Signatera). *Id.* at 98:6-99:17. But MolDX's evaluation process could not, and thus did not, begin until the Parikh Study published four months later in April 2021. The Parikh Study was (and remains to this day) the only clinical validation data Guardant submitted.

[redacted] Ex. 9 (GHI00014465). [redacted] *See, e.g.*, Ex. 13 (GHI00053112) at 12-15; Ex. 14 (GHI00063255) at 61-62. [redacted] *Id.* at 58-59. In August 2022, MolDX approved Reveal for ***partial*** Medicare coverage only.[3]

Despite lacking any admissible evidence in support, Guardant places all the blame on Natera for this "delayed" approval. *See* Ex. 2 (Eltoukhy Dep. Tr.) at 362:22-363:1 [redacted] *see also id.* at 122:17-123:2, 363:12-19. Even Guardant's perception of a relative "delay" is speculative—Guardant has no admissible evidence to prove what the baseline time-to-approval for Reveal would be. Indeed, before commercially releasing Reveal, Guardant knew MolDX approval for Reveal was "not guaranteed." *See* Ex. 5 (McCoy Dep. Tr.) at 68:19-69:12; Ex. 11 (GHI00036362) at 82 (identifying [redacted]

[3] Guardant Health Receives Medicare Coverage for Guardant Reveal™ Test (Aug. 2, 2022) available at https://investors.guardanthealth.com/press-releases/press-releases/2022/Guardant-Health-Receives-Medicare-Coverage-for-Guardant-Reveal-Test/default.aspx.

[redacted]

[redacted]). To this day, Reveal's use for surveillance monitoring for CRC recurrence has not been approved by MolDX for Medicare reimbursement. *See* Ex. 7 (Talasaz Dep. Tr.) at 152:13-22, 154:14-24; Ex. 14 (GHI00063255) at 62-63.

III. ARGUMENT

A. [redacted]

Guardant's purported evidence and argument about Natera's impact on MolDX is irrelevant and should be excluded under Federal Rules of Evidence 401 and 402. [redacted]. And for good reason—they are not actionable under the Lanham Act because they are not commercial advertisements or promotion. *Nat'l Servs. Grp., Inc. v. Painting & Decorating Contractors of Am., Inc.*, No. SACV06-563CJC(ANX), 2006 WL 2035465, at *4 (C.D. Cal. July 18, 2006). [redacted] *See New.Net, Inc. v. Lavasoft*, 356 F. Supp. 2d 1090, 1111 (C.D. Cal. 2004). [redacted], and MolDX does not make purchasing decisions—MolDX is not the purchasing public.

Nor was any evidence or argument on MolDX used in any way to calculate Guardant's purported damages. Guardant's damages expert, Mr. Malackowski, does not rely on Reveal's purported Medicare coverage delay in his damages calculations. While Mr. Malackowski claims that [redacted] of course Guardant's claim for lost profits in this case cannot be based on such ***non-advertising*** conduct, even if there were evidence that Natera contributed to this "delay."

[redacted] are simply not relevant and thus should not be presented or referenced to the jury.

B. Guardant Has No Admissible Evidence that MolDX Was Influenced by Natera

It is black letter law that a witness will be precluded from speculating or voicing suspicions

[redacted]

without personal knowledge of the facts. For example, in *Carmen v. San Francisco Unified School District*, 237 F.3d 1026, 1028 (9th Cir. 2001), the Ninth Circuit affirmed exclusion of plaintiff's testimony on her belief that she was denied a promotion "because of this court case" on a motion for summary judgment. The Ninth Circuit noted that this evidence was properly excluded under Rule 602 because "there was no evidence in the deposition or anywhere else in the summary judgment papers of any basis in personal knowledge for the plaintiff's subjective belief about the defendant's motive." *Id.* This Court has already cautioned that witnesses may not offer testimony on "others' motives, knowledge, or intent." Dkt. 323 at 15.

Here, there is no evidence [redacted] had any effect on the Medicare coverage approval of Reveal. Guardant's witnesses repeatedly admitted they have no evidence Natera had ***any impact*** on MolDX, and in fact affirmed that MolDX exercises independent judgment. For example, when asked directly whether he has "any evidence that there's some kind of implicit or unconscious bias [redacted] driving MolDX's decision with regard to Reveal and Medicare coverage," Guardant's 30(b)(6) witness Mr. McCoy testified, "I don't have any direct evidence to that case." Ex. 5 (McCoy Dep. Tr.) at 194:16-19. He also confirmed that MolDX told Guardant unequivocally that it would ***not consider*** [redacted] only relied on peer-reviewed data to make determinations about Reveal:

> Q. Yeah, so I heard you say that [redacted] only relied on the peer-reviewed data to make determinations about Reveal; right?
>
> A. ***That's MolDX's standard response, is to state that they only look at peer-reviewed published data, so that is their verbal statement. What they actually did read and how they thought about it and whether or not -- how it was reviewed, I can't tell you.*** What I can tell you is that there -- some of the responses that came to us were fairly similar to some of the critiques that our assay had had by Natera.[4]

Id. at 193:10-193:22 (emphasis added); *see also id.* at 190:21-191:10 ("They say that they only review peer-reviewed published evidence, and so ***they did dismiss the fact that*** [redacted] ***was part of their ongoing consideration for review of our tests***.")(emphasis added);

[4] All emphasis added unless otherwise noted.

283:25-284:9 ("MolDX has stated that ***they don't listen to commentary from competitor products***. That is my understanding of how they've communicated the process.")(emphasis added).

Guardant's association of MolDX's responses with cannot establish MolDX was untruthful in its statements that it only looks at peer-reviewed, published data or that On the contrary, and MolDx's concerns about the Parikh Study show that those critiques were based on objective and legitimate concerns shared by others in the field. Ex. 9 (GHI00014465) at 65. As reasons for this determination, MolDX stated, among other things, that it and further that it —i.e., the Parikh Study. *Id.* at 65-67. On the latter point, MolDX enumerated its concerns and concluded that it *Id.* at 66.

Other Guardant witness confirmed Guardant has no factual basis on which to allege that Natera impacted MolDx's evaluation of Reveal. Guardant's CEO Dr. Eltoukhy testified that Ex. 2 (Eltoukhy Dep. Tr.) at 121:14-23 Guardant's other CEO Dr. Talasaz testified Ex. 7 (Talasaz Dep. Tr.) at 168:2-9.

In short, the record is entirely devoid of any admissible evidence that the independent,

[redacted]

objective, technically specialized organization MolDX, which is charged with important decision-making authority over public spending via Medicare coverage determinations, was influenced by Natera, much less that it was Natera that caused any purported relative "delay" in Medicare reimbursement for Reveal. Any other insinuation by Guardant's witnesses is not evidence—it is nothing more than self-serving speculation about MolDX's approval timeline, as well as MolDX's motives, knowledge, or intent—and should be excluded.

C. Rebutting Guardant's Unfounded Arguments Will Confuse the Jury, Waste Time, and Prejudice Natera

Even assuming Guardant's speculation about Natera's impact on MolDX's decision-making was relevant, admissible evidence (it is not), it should be excluded because any possible marginal probative value is heavily outweighed by the danger of confusing the issues, misleading the jury, wasting time, and undue prejudice to Natera. Rebutting Guardant's baseless theory will necessitate a full-blown mini-trial explaining to the jury highly complex regulatory issues involving Medicare reimbursement and the MolDX Program administered by Palmetto GBA. It also will require walking through the lengthy history of the back-and-forth between Guardant and MolDX regarding Reveal, including the numerous technical analyses and rejections. Natera will have to reconstruct the timeline and explain all the reasons why it was the uncertainties, concerns, and questions about Guardant's data including the Parikh Study—[redacted] that held up Reveal's (partial) reimbursement—to the extent there even was "delay" versus just the normal process timeline. Natera will be unduly prejudiced by having to take time from other relevant issues to rebut the false and unsupported assertion that Natera influenced MolDX, especially when [redacted]

IV. CONCLUSION

For at least the reasons stated above, Natera's motion *in limine* should be granted.

[redacted]

DATED: May 26, 2023

Respectfully submitted,

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.,

Plaintiff,

vs.

NATERA, INC.,

Defendant.

Case No. 3:21-cv-04062-EMC

PLAINTIFF GUARDANT HEALTH, INC.'S RESPONSE IN OPPOSITION TO NATERA'S MOTION IN LIMINE NO. 2 TO EXCLUDE EVIDENCE OR ARGUMENT THAT NATERA HAD ANY EFFECT ON MOLDX'S EVALUATION OF REVEAL FOR MEDICARE APPROVAL

Pretrial Conference:
Date: June 28, 2023
Time: 3:00 p.m.
Place: Courtroom 5

Guardant Health, Inc. (Guardant) opposes Natera's Motion *in Limine* No. 2 seeking to exclude evidence or argument that Natera had any effect on MolDX's evaluation of Reveal for Medicare Approval ("Natera MIL No. 2").

I.INTRODUCTION

As Guardant explained in opposing Natera's summary judgment motion, because Medicare coverage represents "a stamp of approval," it is "absolutely" a "key element" for a successful assay. Ex. 1448, McCoy Dep. 178:16-25; *id.* at 179:6-25 (coverage is a "volume driver" and "most likely will increase the likelihood of [doctors] ordering a test."); Ex. 1394, Eltoukhy Dep. 137:4-9. [redacted] Ex. 1397, NATERA_004320, forwarding Ex.1398, NATERA_004321. [redacted] Ex. 444, NATERA_452357 (Jun. 16, 2021) at 452358-59; [redacted] Ex. 144, NATERA_460887 (Oct. 12, 2021); Ex. 1390, Moshkevich Dep. 285:18-288:25.

Natera's lobbying against Reveal coverage succeeded. [redacted] MolDX delayed coverage for Reveal for more than a year, [redacted]. Ex. 423, GHI00053112, at 53114-15 (Jun. 28, 2021); Ex. 1448, McCoy Dep. 193:20-22 (noting similarity of MolDX's responses [redacted]); 194:1-15. Guardant provided MolDX significant additional analyses of the same Parikh data to support

coverage over the next year. Ex. 423 at GHI00053112-13 (Oct. 11, 2021); Ex. 424, GHI00053116 [redacted] Ex. 427, GHI00047547 [redacted] Aug. 2021); Ex. 423, GHI00053112 [redacted] Ex. 1032, GHI00063283 at 284-299 [redacted] MolDX ultimately agreed that – [redacted] – Guardant had provided sufficient clinical validation data to support Medicare coverage for Reveal. When MolDX finally awarded coverage for Reveal in July 2022 for fee-for-service Medicare patients with stage II or III colorectal cancer (with a retroactive effective date of December 2021), the decision was made without submission of any additional clinical validation data beyond what Guardant had originally provided, i.e., the Parikh Study.

II. ARGUMENT

A. [redacted]

Natera's insistence that [redacted] Natera MIL No. 2 at 4, is wrong. [redacted] These are also the same comparative statements that form the basis of Guardant's false advertising claims against Natera, and that the Court has already determined may go to the jury. Dkt. 329 at 15 ("a jury could find that Natera's advertising statement comparing

presurgical sensitivities is literally false by necessary implication"); 19 ("reasonable jury could find that Natera's "serial longitudinal sensitivity" claim is literally false by necessary implication"); 21 ("reasonable jury could find that the lead time comparison is false by necessary implication").

Second, Natera's [redacted] Ex. 284, NATERA_345228 (emphasis added). Whether or not [redacted] Guardant should be permitted to show the jury evidence reflecting the full extent of [redacted] Ex. 134, NATERA_439539 and impede its launch of Reveal, including but not limited to its dissemination of its false comparative advertising purporting to contrast the "performance" of Signatera and Reveal. At a minimum, this evidence is relevant to whether Natera's conduct merits a finding that the case is "exceptional." *SunEarth, Inc. v. Sun Earth Solar Power Co., Ltd.*, 839 F.3d 1179, 1180 (9th Cir. 2016) (case may be exceptional if the defendant engaged in "malicious, fraudulent, deliberate or willful" conduct).

In fact, [redacted]"[1] For representations to constitute "commercial advertising or promotion" under the Lanham Act's false advertising provision, they must be: (1) commercial speech; (2) by a defendant who is in commercial competition with plaintiff; (3) for the purpose of influencing consumers to buy defendant's goods or services; and (4) disseminated sufficiently to relevant purchasing public to constitute advertising or promotion within that industry. *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir. 1999)[2]. [redacted]—which contain the same false comparisons as its direct

[1] Natera's bald claim that [redacted] Natera MIL No. 2 at 4 (emphasis in original), is illogical, cites no authority and fails. But even if it were true, it would not be a reason to exclude evidence of [redacted] from evidence.

[2] Although subsequent Ninth Circuit decisions have questioned, without deciding, whether "the defendant is in commercial competition with the plaintiff," element survives the Supreme Court's decision in *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, (2014), *see Ariix, LLC v. NutriSearch Corp.*, 985 F.3d 1107, 1120 (9th Cir. 2021), there is no dispute that Natera and Guardant are "in commercial competition."

communications to several thousands of oncologists—[redacted] Natera MIL No. 2 at 4, is wrong. Commercial speech "is not "strictly limited to the core segment of speech that proposes a commercial transaction;" rather it is "commercial in its content if it is likely to influence consumers in their commercial decisions." *New.net, Inc. v. Lavasoft*, 356 F. Supp.2d 1090, 1111 (N.D. Cal. 2004) (cited by Natera). Here, [redacted] both MoldDX's coverage of Reveal and subsequent sales of Reveal. Natera's claim that "MolDX does not make purchasing decisions," is also incorrect. It is undisputed that MolDX decides whether Medicare will pay for (i.e., purchase) diagnostic tests ordered by physicians for their Medicare-eligible patients. On their face, [redacted], Ex. 1398, NATERA_004321, and that Signatera should maintain its *de facto* monopoly as the only Medicare-reimbursed ctDNA test for minimal residual disease in colorectal cancer available on the market. Moreover, as Guardant's Vice President of Reimbursement testified,

> Medicare approval drives not only the ability to get paid for the product, but it's also a mechanism to show an ordering physician who may not have read all the clinical literature around it that the service had been reviewed by an evidentiary review committee and it had a stamp of approval from them.

Ex. 1448, McCoy Dep. at 178:19-24. [redacted], Ex. 276, NATERA_342153 (Jan. 22, 2021) at 342153, and [redacted]

B. The Jury Should Be Able to Consider the Evidence And Draw Its Own Conclusions as to Whether MolDX was Influenced by Natera

Natera's argument that because the Rules of Evidence preclude ***witnesses*** from offering ***opinions*** about the state of mind of another person, Guardant may not offer other evidence or make any argument about whether MolDX was impacted by [redacted], is also wrong.

Guardant does not need to offer its own witness' opinions about MolDX's state of mind, or the reasons MolDX delayed providing coverage to Reveal, to establish it is more probable than not that [redacted]. As described above, ***documentary*** evidence in the form of emails and letters produced by Natera during discovery shows [redacted]. All of this evidence will be introduced through a knowledgeable ***Natera*** witness at trial.

Guardant will also introduce ***documentary*** evidence concerning the reasons MolDX gave Guardant for initially denying Reveal coverage on June 28, 2021. Ex. 423, GHI00053112, at 53114-15. Guardant's witnesses will also provide testimony about ***their own observations*** about the similarities between [redacted] the concerns expressed by MolDX in its June 28, 2021 letter declining to award Reveal coverage. Ex. 423, GHI00053112, at 53114-15 (Jun. 28, 2021) ("[redacted]") Guardant's witnesses can also provide testimony about ***their own*** contemporaneous suspicions about [redacted]. None of this testimony comprises prohibited opinions about the "state of mind" of a third party.

Natera's further argument that Guardant's witnesses "confirmed Guardant had no factual basis on which to allege that Natera's impacted MolDX's evaluation of Reveal," is also unavailing. Prior to the filing of this lawsuit, Guardant had [redacted]. Moreover, because Natera designated nearly all of its document production "Confidential" or "Highly Confidential-Outside Attorney's

[3] As shown, there is no dispute that [redacted] ***is*** inadmissible hearsay if offered for the truth of the matter, and ***Natera*** should be barred from seeking this testimony from a Guardant witness at trial.

Eyes Only," Guardant's executives have been unable to review the documents Natera produced in discovery. Therefore, Guardant's executives still do not know the extent of [redacted]. But Guardant's lack of knowledge concerning the existence of this evidence does not prohibit Guardant's counsel from presenting this evidence through a Natera witness, or a jury from considering it.

In short, a jury considering [redacted] The jury should be allowed to consider this evidence.

C. Rule 403 Should Not Preclude Evidence Concerning [redacted]

Finally, Natera's contention that evidence concerning [redacted] should be barred by Rule 403 fall flat. Rule 403 authorizes the exclusion of relevant evidence only if "its probative value is *substantially* outweighed by danger of unfair prejudice, confusion of the issues, or misleading the jury or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." FED. R. EVID. 403 (emphasis added). In weighing the probative value of the evidence against the dangers and considerations enumerated in Rule 403, the general rule is that the balance should be struck in favor of admission. *U.S. v. Crosby*, 75 F.3d 1343, 1347 (9th Cir. 1996). "The exclusion of relevant evidence pursuant to Rule 403 "is an extraordinary remedy to be used sparingly because it permits the trial court to exclude otherwise relevant evidence." *U.S. v. Mende,* 43 F.3d 12981302 (9th Cir. 1995) (citations and quotations omitted); *see also U.S. v Hankey*, 203 F.3d 1160, 1172 (9th Cir. 2000) ("Relevant evidence is inherently prejudicial, but it is only *unfair prejudice, substantially outweighing probative value* which permits exclusion of relevant matter.") (emphasis added, quotation omitted).

Natera's contention that allowing Guardant to present evidence of [redacted] will "require a full-blown mini-trial explaining to the jury highly complex regulatory issues involving Medicare

reimbursement," (Natera MIL No. 2 at 7) is overblown rhetoric. Guardant presented one witness (its Vice President for Reimbursement, Mark McCoy) to discuss the MolDX review process and Guardant's efforts to gain Medicare coverage for Reveal. Natera's witness list describes no Natera witness as knowledgeable about the topic of Medicare, and neither side designated an expert to offer opinions touching on the "highly complex" Medicare approval process for tests like Signatera and Reveal. Introducing evidence about Natera's explicit efforts [redacted]

III. CONCLUSION

For the reasons set forth above, Guardant respectfully requests that the Court ***DENY*** Natera's MIL No. 2.

Dated: June 5, 2023

SHEARMAN AND STERLING, LLP

By: */s/ Saul Perloff*
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